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TRANSMITTAL FORM

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Total Number of Pages in This Submission	4

Application Number	10/659,408
Filing Date	September 10, 2003
First Named Inventor	Parikh, Rajiv
Art Unit	1616
Examiner Name	Alstrum-Acevedo, James Henry
Attorney Docket Number	021956-000500US

ENCLOSURES *(Check all that apply)*

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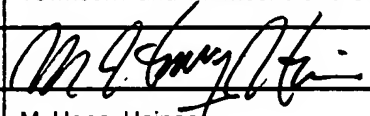
Signature			
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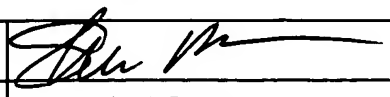
Signature			
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PATENT
Attorney Docket No. 021956-000500US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 4639
Rajiv PARIKH et al.	Examiner: Alstrum-Acevedo, James Henry
Application No.: 10/659,408	Technology Center/Art Unit: 1616
Filed: September 10, 2003	
For: METHOD FOR TREATING AIRWAY DISORDERS	**APPELLANTS' REPLY BRIEF UNDER 37 CFR §41.41**

Mail Stop Appeal Brief
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Sir:

This Reply Brief is submitted in response to the Examiner's Answer mailed on October 13, 2006.

The reasons why the various references do not render the present invention obvious are stated in Appellants' Appeal Brief, but certain points are made in the Examiner's answer that merit this reply.

In the discussion of Moilanen et al. on page 1 of the Answer, the Answer states that

> "it would have been apparent to a skilled artisan that one would use the curve for exhaled nitric oxide (NO) of healthy patients provided by Moilanen as a baseline to ascertain the effectiveness of treatment because the achievement of normative exhaled oxide levels is obviously a goal of these therapeutic methods."

Whether or not this is true, this is not the baseline that is used in Appellants' invention. Appellants' invention develops a baseline that is specific to the individual patient, and will therefore reflect the patient's individual characteristics as well as the patient's disease and treatment history and the patient's specific environment, all of which will affect the baseline. This is not the universal "baseline" that the Answer appears to derive from the disclosure in Moilanen et al. As the Answer acknowledges, that universal "baseline" is averaged over 57 diseased and 57 healthy patients rather than a specific patient on which the information is to be used in the practice of Appellants' invention. The Answer also refers to the curves in FIGS. 2 and 3 of Moilanen et al. as "baselines," but this is a misrepresentation. These curves are not time-generated baselines; the horizontal axis in both Figures is exhalation rate, not time. AS previously explained, the key to the present invention is a patient-specific baseline developed under specified parameters, and the teachings of Moilanen et al. do not suggest the development of such a baseline, much less in the specific manner recited in Appellants' claims, nor the use of such a baseline for tailoring the on-going treatment of the patients' condition.

In its discussion on page 11 of Kharitonov et al., the Answer cites "Kharitonov's teaching of studies of budesonide treatment of asthmatics" and states that it "implies an observed trend." Whether or not multiple measurements were made over a period of time, neither the frequency of those measurements, their use in developing a baseline, nor what could have been done with the baseline, all of which are critical features of Appellants' invention, are anywhere disclosed or suggested. The Answer also uses the word "teaches" in reference to page 537, right column, of Kharitonov et al., as further grounds for the perceived *prima facie* obviousness. This "teach[ing]" is a series of reference citations at the end of the paper under the heading "References," *after* the Summary rather than part of it, and is merely the titles of four earlier papers by the same author. The titles themselves are not disclosures and do not amount to a disclosure of the teachings inside the papers themselves, whatever those teachings may be. AS for the titles themselves, none of the four titles suggest the development of a patient-specific baseline and its use in establishing and controlling treatment in an on-going manner, as Appellants claim.

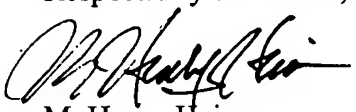
In its discussion of Hampton et al., the Answer states that

"Hampton's method focuses on the analysis of carbon dioxide, but is taught as being useful in the other diagnostic measurements."

To the contrary, there is no reference by Hampton et al. to any analyte other than carbon dioxide, or of extending or applying the teachings therein to any other analyte. The five "steps" listed by the examiner -- i.e., "(i) determining the presence of lung conditions, (ii) determining the severity of the conditions, ..." etc., have nothing to do with the establishment of a baseline and in fact set a protocol without the use of a baseline, a procedure over which Appellants' invention is a distinct improvement.

Appellants submit that the Answer reads teachings into the prior art that are not there, and draws conclusions from a vague perception of obviousness, unsupported by the actual teachings of the references, of Appellants' invention. Appellants' invention is claimed in specific terms and resides in a novel and patient-specific approach to inflammatory lung conditions that resides in the discovery of critical ways to track the patient's own past history and then to use that history in establishing on-going treatment. Reversal of all rejections is once again respectfully requested.

Respectfully submitted,



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